

REMARKS

Applicants submit this Amendment in reply to the Office Action mailed April 25, 2005.

By this Amendment, Applicants have cancelled claims 18-37, 50, and 61, without prejudice or disclaimer, and amended claims 41, 52, and 62. Applicants reserve the right to present the subject matter of claims 18-37, 50, and 61 in another application, for example, an application claiming priority to this application or an application to which this application claims priority.

Before entry of this Amendment, claims 18-37 and 41-68 were pending in this application. After entry of this Amendment, claims 41-49, 51-60, and 62-68 are pending in this application. Claims 41, 52, and 62 are the sole independent claims.

On pages 2-3 of the Office Action, the specification was objected to for allegedly failing to provide antecedent basis for "coronary blockage that is a partial blockage," and claims 50 and 61 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. While Applicants do not necessarily agree that "coronary blockage that is a partial blockage" does not have antecedent basis in the specification and does not comply with the written description requirement, solely in the interests of expediting the prosecution of this application, Applicants have cancelled claims 50 and 61, without prejudice or disclaimer. Accordingly, Applicants respectfully request withdrawal of the objection to the specification and the Section 112, first paragraph rejection.

On page 3 of the Office Action, claims 62-64, 66, and 68 were rejected under 35 U.S.C. §102(a) as being anticipated by WO Publication No. 98/12990 to Sogard et al. ("Sogard"). Applicants respectfully traverse this rejection.

Sogard does not disclose or suggest the claimed invention. For example, independent claim 62 recites a conduit for providing blood flow directly from a heart chamber to a coronary vessel including, among other aspects, "a stent that includes a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and having sufficient flexibility in a compressed state to permit passage to a myocardial site." Sogard does not disclose at least these aspects of independent claim 62 either alone or in combination with the other aspects of independent claim 62.

Indeed, the Office Action does not assert otherwise. Instead, the Office Action recites that "the intended use, as set forth in the claims, carries no weight in the absence of distinguishing structure. Clearly, the device is capable of providing blood flow from a heart chamber to a coronary vessel."

The aforementioned portions of claim 62, however, recite structural features, namely, for example, "a configuration," "sufficient radial strength," and "sufficient flexibility," and thus are not simply intended use aspects. See, e.g., In re Venezia, 189 U.S.P.Q. 149, 151-152 (CCPA 1976) ("Each sleeve of said pair adapted to be fitted over the insulating jacket of one of said cables," "adapted to be affixed," and "adapted to be positioned" are structural limitations.); R.A.C.C. Industries Inc. v. Stun-Tech Inc., 49 U.S.P.Q.2d 1793 (Fed. Cir. 1998) ("A belt of sufficient length to fasten around the torso" is a structural limitation.). In particular, in In re Venezia, the court found "nothing wrong

in defining the structures of the components... in terms of... the attributes they must possess,...” In re Venezia, 189 U.S.P.Q. 149 at 152.

Sogard, however, does not disclose a conduit with the claimed attributes. Instead, Sogard discloses endoprotheses, and particularly endovascular stents for implantation in blood vessels to open or reinforce collapsing or partially occluded sections of the vessel. (See page 1 at lines 18-24.) Sogard also mentions that, in addition to such uses in the vasculature, stents may be used in the urogenital tract and bile duct. (See page 1 at lines 16-18.) Although Sogard discloses that stents are flexible for insertion in blood vessels, Sogard nowhere mentions that such stents have “a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle,” as recited in claim 62. In fact, a conduit according to claim 62 “for providing blood flow directly from a heart chamber to a coronary vessel” experiences stresses significantly different than those typically experienced in blood vessels, the urogenital tract, or the bile duct. The “contractile forces experienced during a cardiac cycle,” especially during systolic contraction of the heart wall, are far different than the pressures experienced in blood vessels, the urogenital tract, or the bile duct. Thus, Sogard does not disclose or suggest stents having “a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle,” as recited in claim 62.

Furthermore, even assuming that one or more recitations of claim 62 are “intended use,” or functional aspects, such aspects still must be given patentable weight insofar as the allegedly corresponding structure in the prior art must be capable of performing the function in order to anticipate the functional aspect. While invoking

functional aspects “may render a claim quite broad,” as “[b]y its own literal terms a claim employing such language covers any and all embodiments which perform the recited function.... This is not to say, however, that every claim containing ‘functional’ terminology is broad. Indeed, in many cases it will be obvious that only a very limited group of objects will fall within the intended category.” In re Swinehart and Sfiligoj, 439 F.2d 210, 169 U.S.P.Q. 226 (CCPA 1971) (emphasis removed). See also, In re Danly, 263 F.2d 8445, 120 U.S.P.Q. 528 (CCPA 1959) (“It is noted that claims 3 through 7 do not positively recite a source of alternating current as an element of the claims, but employ such expressions as ‘means for connecting the ends of the series-connected tie rods to a source of alternating current potential.’ While it may be literally true that any piece of wire could be used to perform that function, we are of the opinion that the quoted expression, taken in context, limits the claims to a construction in which a connection with a source of alternating current is actually made, since any other interpretation would render the quoted expression virtually meaningless.”).

Accordingly, the corresponding structure in Sogard must be capable of meeting the allegedly functional aspects of claim 62. As the stent in Sogard has not been shown as being capable of at least “having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle” for at least the reasons set forth above, Sogard does not anticipate claim 62.

Without any support, however, the Office Action asserts that “[c]learly, the [Sogard] device is capable of providing blood flow from a heart chamber to a coronary vessel.” Applicants understand that the Examiner may be taking the position that Sogard inherently discloses a stent with “a configuration having sufficient radial strength

to resist deformation from contractile forces experienced during a cardiac cycle.” The fact, however, that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result of characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). “To establish inherency, the extrinsic evidence ‘must make clear that missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed Cir. 1999) (citations omitted) (emphasis added). As the Office Action does not cite any evidence to support that any stent in Sogard necessarily includes “a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle,” Sogard does not inherently disclose these aspects of claim 62. Indeed, as set forth above, a conduit according to claim 62 “for providing blood flow directly from a heart chamber to a coronary vessel” experiences stresses significantly different than those typically experienced in blood vessels, the urogenital tract, or the bile duct, the body vessels disclosed in Sogard. Since the “contractile forces experienced during a cardiac cycle,” especially during systolic contraction of the heart wall, are far different than the pressures experienced in blood vessels, the urogenital tract, or the bile duct, the Sogard stents do not necessarily have “a configuration having sufficient radial strength to resist deformation from contractile forces experienced during the cardiac cycle.” This precludes a finding that the alleged functional aspects of claim 62 are inherently in the Sogard stents.

For all of the above reasons, claim 62 is distinguishable from Sogard.

On pages 3-4 of the Office Action, claims 65 and 67 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sogard in view of U.S. Patent No. 5,637,112 to Tartaglia et al. ("Tartaglia"). As the Office Action cites Tartaglia for its alleged disclosure of the use of heparin on a covered stent, and not to remedy the aforementioned deficiencies of Sogard, Applicants respectfully assert that a *prima facie* case of obviousness has not been established for dependent claims 65 and 67, and thus respectfully request withdrawal of the Section 103(a) rejection based on Sogard and Tartaglia.

On pages 4-5 of the Office Action, claims 41, 43, 47-49, 51-53, 55, and 58-60 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,429,144 to Wilk ("Wilk") in view of U.S. Patent No. 5,755,682 to Knudson et al. ("Knudson"), and claims 41-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wilk in view of U.S. Patent No. to 5,123,917 to Lee ("Lee"). Applicants respectfully traverse these rejections for at least the following reasons.

The Office Action does not set forth a proper case of *prima facie* obviousness. For example, one of the requirements for setting forth a proper case of *prima facie* obviousness is that the prior art references must disclose or suggest each and every aspect of the claimed invention. M.P.E.P. §2142. In this case, the Office Action fails to do so.

For example, independent claim 41 recites a method including, among other aspects, "providing a stent that ... includes a covering on an inner surface portion and an outer surface portion of the stent." In another example, independent claim 52 recites a method including, among other aspects, "applying a covering to an inner surface

portion and an outer surface portion of the stent.” The Office Action has not shown how the prior art discloses or suggests at least these respective aspects of independent claims 41 and 52.

Page 4 of the Office Action recites that Wilk “discloses (col. 8, lines 48-55) the stent has an inner and outer covering of natural tissue, Figs. 8A, 8B, 9.” This is incorrect. Fig. 9 of Wilk discloses “an outer layer 80 of interwoven helical strands of biocompatible material” and an “inner layer 82” which “is a vascular graft taken from the patient prior to the by-pass operation.” Accordingly, even assuming that outer layer 80 and inner layer 82 respectively correspond to the stent and the covering as set forth in each of claims 41 and 52, inner layer 82 only covers an inner portion of outer layer 80, and not “an inner surface portion and an outer surface portion” as set forth in each of claims 41 and 52. Applicants note that “Fig. 9 is a schematic side perspective view, on an enlarged scale and **partially broken away**, of a modified coronary by-pass stent.” (Wilk at col. 5, lines 23-26; emphasis added.) Since Fig. 9 is a partially broken away view, the portion of inner layer 82 that may appear to be on an outer portion of outer layer 80 in Fig. 9 is in fact also disposed on the inner portion of outer layer 80.

Additionally, Figs. 8A and 8B of Wilk disclose “a vascular graft layer 84 inside stent segments 72.” Even assuming that stent segments 72 and vascular graft layer 84 respectively correspond to the stent and the covering as set forth in each of claims 41 and 52, vascular graft layer 84 only covers an inner portion of stent segments 72, and not “an inner surface portion and an outer surface portion” as set forth in each of claims 41 and 52.

Moreover, the Office Action does not refer to Knudson or Lee as remedying these deficiencies of Wilk. Indeed, the Office Action cites Knudson and Lee for other purposes. Accordingly, for at least these reasons, a proper case of *prima facie* obviousness has not been established for independent claims 41 and 52 and their respective dependent claims, and thus the Section 103(a) rejections based on Wilk, Knudson, and Lee should be withdrawn.

Claims 42-49, 51, 53-60, and 63-68 depend from one of independent claims 41, 52, and 62, and are therefore allowable for at least the same reasons that each respective independent claim is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references, and therefore at least some also are separately patentable.

In view of the foregoing remarks, Applicants submit that this claimed invention is neither anticipated nor rendered obvious in view of the art cited against this application. Applicants therefore request the withdrawal of the final rejection, and the timely allowance of pending claims 41-49, 51-60, and 62-68.

The Office Action contains other characterizations and assertions regarding the claims and the cited art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification and claims in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in

the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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